K000937
Page 1 of 2

MAY 2 5 2000

510(k) SUMMARY

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is:_____.

Submitted by: InVitroCare, Inc.
11408 Sorrento Valley Rd.
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Contact: Robert E. Lovins, PhD

Date Submitted: October 13,1999

Device Identification:

Trade Name: IVC TWO Medium

Common Name: In vitro embryo culture medium

Classification Name: Reproductive Media (21CFR, 886.6180)

Predicate Device:

Notice of Final Rule, 63 FR 48428, Docket number 97N-0335 and 510(k) Reference Number K983589

Description:

IVC TWO is a synthetic, defined culture medium intended for use in assisted reproductive technology procedures. The formulation of IVC TWO is substantially equivalent to the glucose and phosphate free HTF formulation published by Quinn et al (Quinn P, Moinipanah R, Steinberg J, Weathersbee P: Fertil Steril 1995;63:922-924). IVC TWO is designed to support early stages of embryonic growth (up to four days post-fertilization). IVC TWO has been formulated without phosphate, which may be detrimental to embryo blastocyst development. IVC TWO may be used as a stand alone medium or as the first stage of a sequential medium protocol.

Intended Use:

IVC TWO is intended for use in assisted reproductive procedures that may involve the manipulation of gametes and embryos. These procedures include the use of IVC TWO as an embryo culture medium through day four of embryo growth and development.

Design Characteristics:

After retrieval of oocytes from the patient, the oocytes are placed in a culture dish containing IVC TWO medium which has been supplemented with an appropriate amount of protein. Fertilization is allowed to take place and the zygote is transferred to a fresh culture dish containing fresh IVC TWO medium and protein. The culture dish is placed into a carbon dioxide incubator and the embryo is allowed to develop, in vitro, until the desired stage of embryonic development has been achieved, usually up to three days post fertilization. At that time, the embryo may either be transferred to the patient or to a second, more complex culture medium for continued in vitro culture.

Performance Data:

IVC TWO is subjected to cytotoxicity testing and sperm motility/hyperactivation analysis. Each lot of IVC TWO is also assayed by a mouse embryo assay prior to its release to market. These assays assure that the product is both functional for its intended use, the support of embryonic growth and that no toxic components are present in the formulation. Phosphate free HumanTubal Fluid medias have been used in a variety of clinical settings, for the intended use for a number of years. In that time the product has become the standard media used for the early development of human embryos in vitro.

Additional Information:

Mouse embryo testing will be performed as a condition of release for IVC TWO medium as well as endotoxin and sterility testing. Results of all release assays will be reported on a lot-specific certificate of analysis and will be indicated on the labeling.

Conclusion:

The conclusion from performance testing, as well as a review of published historical information contained in the professional literature shows that IVC TWO is suitable for its intended use and meets the criteria outlined in the Final Rule, 63 FR48428, Docket number 97N-0335.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 5 2000

Robert E. Lovins, Ph.D.
President
InVitroCare, Inc.
11408 Sorrento Valley Road
Suite 202
San Diego, CA 92121

Re: K000937
IVC Two Medium (embryo culture medium)
Dated: March 22, 2000
Received: March 23, 2000
Regulatory Class: II
21 CFR §884.6180/Procode: 85 MQL

Dear Dr. Lovins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

INDICATIONS FOR USE STATEMENT (Page 1 of 1)

510(k) number: K000937

Device Names: IVC TWO Medium

Indications for Use:

IVC TWO Medium is intended for use in assisted reproductive technology procedures that involve the manipulation of gametes and embryos. Specifically, IVC TWO is intended for use as a embryo culture medium through day four of embryo development.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000937

Prescription Use
(per 21 CFR 801.109)